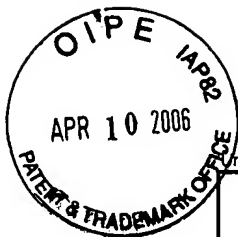


04-12-06

JW



PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

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<h1 style="text-align: center;">TRANSMITTAL FORM</h1> <p style="text-align: center;">(to be used for all correspondence after initial filing)</p>		Application Number	10/773,618
		Filing Date	February 6, 2004
		First Named Inventor	Thomas W. DUBENSKY, Jr.
		Art Unit	1645
		Examiner Name	J. Graser
Total Number of Pages in This Submission	15 + 55 Refs.	Attorney Docket Number	282172002800

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement (Supplemental - 4 pages) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1. Form PTO/SB/08a/b + copy (8 pages) 2. Cover Sheet for References Vol. 1 of 2 (1 page) 3. Cover Sheet for References Vol. 2 of 2 (1 page) 4. Fifty-five (55) References 5. Return Receipt Postcard
<div style="border: 1px solid black; padding: 5px;">Remarks</div>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MORRISON & FOERSTER LLP (Customer No. 25226)		
Signature			
Printed name	Alicia J. Hager		
Date	April 10, 2006	Reg. No.	44,140

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 596702491 US, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: April 10, 2006

Signature:

(Georgina Matos)

14  
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Dated: April 10, 2006 Signature: Georgina Matos  
(Georgina Matos)

Patent  
Docket No. 282172002800

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Thomas W. DUBENSKY, Jr. et al.

Examiner: J. Graser

Serial No.: 10/773,618

Group Art Unit: 1645

Filing Date: February 6, 2004

For: MODIFIED FREE-LIVING MICROBES,  
VACCINE COMPOSITIONS AND  
METHODS OF USE THEREOF

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

Applicants note that the document submitted herewith as "Brockstedt, D. et al. (March 2003). "Recombinant Attenuated *Listeria monocytogenes* Elicits Robust Cellular Immune Response to Tumor-Associated Antigen in *Listeria* Immune Mice," *Proceedings of the American Association for Cancer Research, 94th Annual Meeting, April 5-9, 2003, Toronto, Ontario, Canada, 44:194, Abstract No. 851, one page*" (Ref. No. 15) was previously submitted with the Information Disclosure Statement filed on July 21, 2004, but was incorrectly identified on the Form PTO-1449

filed on that date as "Brockstedt, D. et al. (March 10, 2003). "Recombinant Attenuated *Listeria monocytogenes* Elicits Robust Cellular Immune Response to Tumor-Associated Antigen in *Listeria* Immune Mice," Abstract #851, *posted online at Days of Molecular Symposium* website, one page" (Ref. No. 76) due to inadvertent error.

Applicants would also like to draw the Examiner's attention to the fact that Ref. No. 3 submitted herewith is a translation of Ref. No. 10 (FR 2 686 896) previously submitted on January 6, 2005. Ref. No. 4 submitted herewith is a translation of Ref. No. 14 (WO 99/29884) submitted on January 6, 2005. Ref. No. 5 submitted herewith is a translation of Ref. No. 48 (WO 01/27295) submitted on July 21, 2004.

Applicants would also like to draw the Examiner's attention to the co-pending applications listed below:

Application Serial No. 10/883,599, filed June 30, 2004 by Dubensky, Jr. et al. and

Application Serial No. 11/173,770, filed June 30, 2005 by Dubensky, Jr. et al.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.

- ☐ A fee is required. A check in the amount of \_\_\_ is enclosed.
- ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

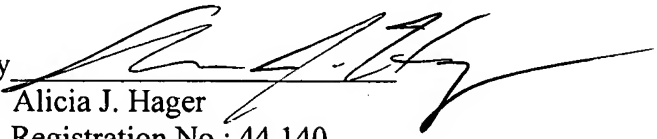
In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including

extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 282172002800.

Dated: April 10, 2006

Respectfully submitted,

By

  
Alicia J. Hager

Registration No.: 44,140

MORRISON & FOERSTER LLP  
755 Page Mill Road  
Palo Alto, California 94304-1018  
(650) 813-4296



ALTERNATIVE TO PTO/SB/08a/b (07-05)

<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/773,618
				Filing Date	February 6, 2004
				First Named Inventor	Thomas W. DUBENSKY, Jr.
				Art Unit	1645
				Examiner Name	J. Graser
Sheet	1	of	4	Attorney Docket Number	282172002800

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	US-2005/0249748-A1	11-10-2005	Dubensky Jr. et al.	
	2.	US-2005/0281783-A1	12-22-2005	Kinch et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	3.	FR-2 686 896-A1	08-06-1993	Pasteur Institute		✓
	4.	WO-99/29884-A2	06-17-1999	Von Eichel-Streiber et al.		✓
	5.	WO-01/27295-A1	04-19-2001	Deutsches Krebsforschungszentrum Stiftung Des Offentlichen Rechts		✓
	6.	WO-02/33109-A2, A3	04-25-2002	Bioteknologisk Institut		
	7.	WO-03/083056-A2, A3	10-09-2003	Research Development Foundation		
	8.	WO-2004/011492-A1	02-05-2004	Commonwealth Scientific and Industrial Research Organisation		
	9.	WO-2005/009463-A2, A3	02-03-2005	Cerus Corporation		
	10.	WO-2005/037233-A2, A3	04-28-2005	Medimmune, Inc.		
	11.	WO-2005/071088-A2, A3	08-04-2005	Cerus Corporation		
	12.	WO-2005/092372-A2	10-06-2005	Cerus Corporation et al.		

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author ( in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	13.	Barnard, J.P. et al. (February 1999). "Vaccination Against Anthrax with Attenuated Recombinant Strains of <i>Bacillus anthracis</i> That Produce Protective Antigen," <i>Infection and Immunity</i> 67(2):562-567.		
	14.	Bielecki, J. et al. (May 10, 1990). " <i>Bacillus subtilis</i> Expressing a Haemolysin Gene from <i>Listeria monocytogenes</i> Can Grow in Mammalian Cells," <i>Nature</i> 345(6271):175-176.		
	15.	Brockstedt, D. et al. (March 2003). "Recombinant Attenuated <i>Listeria monocytogenes</i> Elicits Robust Cellular Immune Response to Tumor-Associated Antigen in <i>Listeria</i> Immune Mice," <i>Proceedings of the American Association for Cancer Research, 94th Annual Meeting</i> , April 5-9, 2003, Toronto, Ontario, Canada, 44:194, Abstract No. 851, one page.		
	16.	Brockstedt, D.G. (Date Unknown). "Listeria-CEA Vaccine-Infected DC for Cancer Therapy," Abstract for Grant No. 1R43CA108026-01 located at < <a href="http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6787426&amp;p_grant_num=1R43C...">http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6787426&amp;p_grant_num=1R43C...</a> > last visited June 27, 2004. two pages.		

Examiner Signature		Date Considered	
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pa- 1054139

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/773,618
				Filing Date	February 6, 2004
				First Named Inventor	Thomas W. DUBENSKY, Jr.
				Art Unit	1645
				Examiner Name	J. Graser
Sheet	2	of	4	Attorney Docket Number	282172002800

17.	Brockstedt, D.G. et al. (August 2005) "Killed but Metabolically Active Microbes: A New Vaccine Paradigm For Eliciting Effector T-Cell Responses and Protective Immunity," <i>Nature Medicine</i> 11(8):853-860.
18.	Brossier, F. et al. (August 1999). "Antigen Delivery by Attenuated <i>Bacillus anthracis</i> : New Prospects in Veterinary Vaccines," <i>Journal of Applied Microbiology</i> 87(2):298-302.
19.	Brown, D.P et al. (May 1988). "Site-Specific Integration in <i>Saccharopolyspora erythraea</i> and Multisite Integration in <i>Streptomyces lividans</i> of Actinomycete Plasmid pSE101," <i>J. Bacteriology</i> 170(5):2287-2295.
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21.	Conradt, P. et al. (1999). "Cytolytic T-Cell Responses to Human Dendritic Cells and Macrophages Infected with <i>Mycobacterium bovis</i> BCG and Recombinant BCG Secreting Listeriolysin," <i>Microbes Infect.</i> 1:753-764.
22.	Dubensky, T.W. (Date Unknown). "Listeria-Based Vaccines for Ovarian Cancer Therapy," Abstract for Grant No. 1R43CA101421-01 located at < <a href="http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6645288&amp;p_grant_num=1R43CA...">http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6645288&amp;p_grant_num=1R43CA...</a> > last visited November 3, 2004, two pages.
23.	Dubensky, T.W. (Date Unknown). "Psoralen-Killed, Metabolically-Active Anthrax Vaccine," Abstract for Grant No. 1U01AI061199-01 located at < <a href="http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6818020&amp;p_grant_num=1U01AI...">http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6818020&amp;p_grant_num=1U01AI...</a> > last visited November 3, 2004, two pages.
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26.	Friedman, R.S. et al. (November 2000). "Induction of Human Immunodeficiency Virus (HIV)-Specific CD8 T-Cell Responses by <i>Listeria monocytogenes</i> and a Hyperattenuated <i>Listeria</i> Strain Engineered to Express HIV Antigens," <i>Journal of Virology</i> 74(21):9987-9993.
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28.	Giedlin, M.A. (Date Unknown). "Use of <i>Listeria</i> as Colon Cancer Vaccine Adjuvants," Abstract for Grant No. 1R43CA101378-01 located at < <a href="http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6645212&amp;p_grant_num=1R43CA...">http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?testkey=6645212&amp;p_grant_num=1R43CA...</a> > last visited November 3, 2004, two pages.
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Examiner Signature		Date Considered	
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pa- 1054139

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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Sheet	3	of	4	Attorney Docket Number	282172002800

32.	Guerry, P. et al. (February 1994). "Development and Characterization of <i>recA</i> Mutants of <i>Campylobacter jejuni</i> for Inclusion in Attenuated Vaccines," <i>Infection and Immunity</i> 62(2):426-432.
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37.	Kiessling, A. et al. (December 1, 2002). "Prostate Stem Cell Antigen: Identification of Immunogenic Peptides and Assessment of Reactive CD8 <sup>+</sup> T Cells in Prostate Cancer Patients," <i>Int. J. Cancer</i> 102(4):390-397.
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42.	McCloy, E.W. (1951). "Studies on a Lysogenic <i>Bacillus</i> Strain. I. A Bacteriophage Specific for <i>Bacillus anthracis</i> ," <i>J. Hyg.</i> 49:114-125.
43.	Mollet, B. et al. (July 1993). "Directed Genomic Integration, Gene Replacement, and Integrative Gene Expression in <i>Streptococcus thermophilus</i> ," <i>J. Bacteriology</i> 175(14):4315-4324.
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Examiner Signature		Date Considered	
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Sheet	4	of	4	Attorney Docket Number	282172002800

	52.	Van Pinxteren, L.A.H. et al. (2000). "Control of Latent <i>Mycobacterium tuberculosis</i> Infection is Dependent on CD8 T cells," <i>Eur. J. Immunol.</i> 30:3689-3698.	
	53.	Welch, M.D. et al. (July 3, 1998). "Interaction of Human Arp2/3 Complex and the <i>Listeria monocytogenes</i> ActA Protein in Actin Filament Nucleation," <i>Science</i> 281:105-108.	
	54.	Winterling, K.W. et al. (April 1998). "The <i>Bacillus subtilis</i> DinR Binding Site: Redefinition of the Consensus Sequence," <i>J. Bacteriol.</i> 180(8):2201-2211.	
	55.	Wirth, R. et al. (March 1986). "Highly Efficient Protoplast Transformation System for <i>Streptococcus faecalis</i> and a New <i>Escherichia coli</i> - <i>S. faecalis</i> Shuttle Vector," <i>J. Bacteriol.</i> 165(3):831-836.	
	56.	Written Opinion issued for PCT Application No. PCT/US2004/003429 filed February 6, 2004, mailed December 7, 2004, 9 pages.	
	57.	Written Opinion issued for PCT Application No. PCT/US2005/002987 filed February 2, 2005, mailed January 19, 2006, 9 pages.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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